

Remarks

Claims 1 to 35 were pending. By this Amendment, claims 2 to 7 have been cancelled and claim 1 has been amended. As no new matter has been added thereby, entry of the amendments is respectfully requested. Claims 1 and 8 to 35, as amended, are now pending and before the Examiner.

The Examiner objected to the specification in that it contains numerous incorporations by references and requested that the specification be amended to include such material in the specification.

In response, applicants traverse the objection. Incorporation by reference is specifically allowed by the rules, whether they are “numerous” or not, and the Examiner has provided no basis for concluding that any of the incorporated references, let alone all of them, are “essential material” and improper. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the objection.

The Examiner rejected claims 1 to 35 as allegedly not enabled under 35 U.S.C. § 112, first paragraph.

In response, applicants have amended claim 1 to respond to the rejection, but also traverse the rejection as improper as set forth below. “When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement”. *In re Wright*, 27 U.S.P.Q. 1510, 1513 (Fed. Cir. 1993)(emphasis added).

In making this rejection, the Examiner alleges that the term “prevent” requires absolute success. Applicants respectfully disagree and request that the Examiner explain why prevention requires absolute success (if so, how can this be proven?), but treatment somehow does not? Applicants maintain that this is an unreasonable interpretation of the meaning of prevention and is accordingly improper. As the Board pointed out in *Ex parte Cho*, Appeal

No: 2001-2646 (Bd. Pat. App. & Int. 2002)(nonprecedential)(copy enclosed for the Examiner's convenience), on page 7, "The examiner has indicated that the claimed methods 'would not be rejected if limited to "treating" pain, asthma and inflammation. ... Logically, if the recited compounds are useful for treating conditions such as pain and inflammation once they exist, they would also be expected to be effective in preventing pain and inflammation, if they were administered before the onset of pain or inflammation." (emphasis in original). Applicants note that the Office has been repeatedly reversed for rejecting for lack of enablement claims directed to compounds having demonstrated pharmaceutical and biological activity. See M.P.E.P. § 2107 (particularly §§ 2107.01 III/IV and 2107.03, discussing the relationship of the utility and enablement requirements and the role of the FDA) and § 2164 (particularly § 2164.06). According, applicants respectfully request that the Examiner reconsider and withdraw the rejection.

The Examiner also rejected claims 1, 2, 4 to 8, and 18 to 32 as allegedly anticipated under 35 U.S.C. § 102(b) over De Gasparo *et al.* (WO 01/76573), in light of Robl *et al.* (U.S. Patent Appl. Pub. No. 2002/0013334).

In response, applicants traverse the Examiner's rejection. De Gasparo *et al.* does not specifically disclose the combination of telmisartan and simvastatin anywhere and the Examiner has not pointed out how De Gasparo *et al.* thereby anticipates the claimed invention. Accordingly, the anticipation rejection should be reconsidered and withdrawn.

The Examiner also rejected claims 1 to 20 as allegedly unpatentable under 35 U.S.C. § 103(a) over De Gasparo *et al.*, in light of Robl *et al.*, in view of Cecil's Textbook of Medicine (2000), Harlan *et al.* (U.S. Patent Appl. Pub. No. 2001/0006656), and Bohm *et al.* (WO 02/15891*).

Applicants respectfully traverse the rejection. A *prima facie* case of obviousness requires the satisfaction of three criteria: (i) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the

* In the Office Action WO 02/15892 seems to be a typographical error for WO 02/15891, which is consistent with the copy of the reference enclosed and the first inventor's name. Clarification is requested in the next Office Action.

art, to modify the reference or combine reference teachings; (ii) there must be a reasonable expectation of success; and (iii) the references when combined must teach or suggest all of the claim limitations. See M.P.E.P. § 2143. As explained above, De Gasparo *et al.* does not disclose or suggest the specific combination of telmisartan and simvastatin anywhere, nor does Robl *et al.*, Cecil's Textbook of Medicine, Harlan *et al.*, nor Bohm *et al.* provide what De Gasparo *et al.* lacks in providing a motivation, reasonable expectation of success, or teaching or suggestion of all of the claim limitations of the claimed invention.

Furthermore, neither De Gasparo *et al.*, Robl *et al.*, Cecil's Textbook of Medicine, Harlan *et al.*, nor Bohm *et al.* teach or suggest that telmisartan increases the expression of genes regulated by the PPARgamma receptor, i.e., an activity known from antidiabetic drugs, which is the reason that telmisartan is a preferred combination partner for simvastatin in the treatment of, e.g., diabetes, and this metabolic activity appears to be unique for telmisartan. Furthermore, neither Harlan *et al.* (disclosing an aerosol formulation of statins), nor Bohm *et al.* (disclosing a combination of telmisartan with ACE inhibitors) do not disclose, suggest, or hint at telmisartan combinations with statins. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

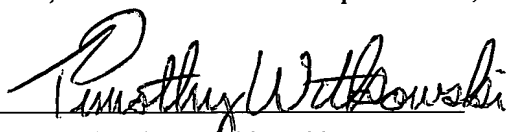
The Examiner also provisionally rejected claims 1 to 35 for nonstatutory obviousness-type double patenting over claims 1 to 18 of U.S.S.N. 10/757,295, in view of Harlan *et al.*; provisionally rejected claims 1, 4 to 6, 9 to 13, and 18 to 26 for nonstatutory obviousness-type double patenting over claims 1 to 10, 12 to 15, and 18 of U.S.S.N. 10/899,784; and provisionally rejected claims 1, 2, 4 to 8, 14 to 19, and 21 to 35 for nonstatutory obviousness-type double patenting over claims 1 to 21 of U.S.S.N. 11/300,947 in view of Drug Facts and Comparisons (1996).

In response, with regard to U.S.S.N. 10/757,295, applicants undertake to file a terminal disclaimer should (1) the instant claims be found otherwise allowable, and (2) applicants determine that U.S.S.N. 10/757,295 poses a double patenting issue at that time. In addition, applicants traverse the remaining provisional double patenting rejections as the Examiner has failed to establish a *prima facie* case of obviousness as required for such double patenting rejections using these applications. With regard to U.S.S.N. 10/899,784, in making this provisional rejection, the Examiner states that "a species will always anticipate a claim to a

genus". This rule, however, does not mean that a genus [U.S.S.N. 10/899,784] always anticipates or renders obvious a species [the instant application] and the Examiner's logic is fallacious and improper. With regard to U.S.S.N. 11/300,947, it claims a combination of telmisartan + HCTZ (diuretic): since it claims no statin, it is unclear how the claims of U.S.S.N. 11/300,947 render the instant claims obvious. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Applicants submit that all the pending claims are allowable and respectfully solicit a Notice of Allowance for all of the pending claims. If the Examiner feels that a telephone interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the attorney below.

Certificate of Mailing Under 37 C.F.R. § 1.8(a)
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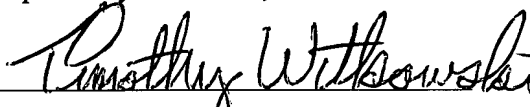


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Dated

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